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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BOULDER, CO 80303

EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,799

Applicant(s)

FARN ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-63 and 66-84 is/are pending in the application.
- 4a) Of the above claim(s) 39-62, 67-71 and 73-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63, 66 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

1. Applicant's response filed on 7/27/04 is acknowledged. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Status of claims

2. Claims 63, 66 and 72 have been amended.
Claims 64-65 have been canceled.
Claims 63, 66 and 72 are under examination as an elected invention.
Claims 39-62, 67-71 and 73-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.
Claims 39-62, 63, 66, 67-71, 72 and 73-84 are pending in the application.

Restriction requirement

3. Applicant requests the examiner to examine claim 67 and states that the claim 67 as amended now makes ^{a contribution} over the prior art, used for the lack of unity. Applicant states that now claim 67 shares special technical features as defined in the PCT Rule 13.2 and cites PCT, Part 2, example 17.

The examiner carefully looked at the claim and reviewed the PCT Rule 13.2 especially PCT, Part 2, example 17. The claim 67 is drawn to a nucleic acid and not to the polypeptide that is elected. Therefore, it is not included along with the claims 63, 66 and 72. Further, it is not correct applying the lack of unity rules PCT Rule 13.2 to the amended claim 67 now because the examiner has properly restricted the original claims, applicant has elected "polypeptide" (said election was made on 11/4/03) and accordingly claims 63, 66 and 72 have been examined (see e 37 CFR 1.142(b) and MPEP § 821.03).

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Specification - Informalities withdrawn

4. In view of the amendment to the specification, specification informalities have been withdrawn.

Claim Rejections - 35 USC 101 withdrawn

5. In view of the amendment, the rejection of record under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC 112 maintained

6. The rejection of claims 63, 66 and 72 under 35 U.S.C. 112, first paragraph written description and enablement is maintained as set forth in the previous office action.

The claims are drawn to an isolated polypeptide comprising the amino acid sequence as set out in SEQ.ID.NO: 5 or a functional fragment thereof, at least 20 amino acids in length which shows immunological cross reactivity with said polypeptide, said polypeptide having haemolysin activity. Claims are also drawn to a composition comprising said polypeptide and optionally a carrier and/or adjuvant.

Claims 63, 66 and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection

The specification broadly describes as part of the invention, an isolated recombinant polypeptide comprising an amino acid sequence, SEQ ID NO: 5, which is encoded by *Moraxella bovis* strain Dalton 2d. The specification also teaches on page 25 that this full-length protein contains 927 amino acids with a molecular weight 98.8 kD. At the amino acid level it appears that this haemolysin gene product shows similarities with a subunit of the RTX and other haemolysins. However, the specification does not teach a functional fragment thereof, at least 20 amino acids in length which shows immunological cross reactivity with said polypeptide, said polypeptide having haemolysin activity.

The actual biological function of the protein represented as SEQ ID NO: 5 is not set forth in this specification. Applicants broadly describe the invention as embracing any deletion by use of language in which a specified percent of amino acids can be changed in the protein. USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled

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in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See Vas-Cath at page 1116).

Thus, an isolated polypeptide comprising the amino acid, SEQ ID NO: 5 and composition comprising said polypeptide meets the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The specification fails to teach polypeptide fragments of SEQ ID NO: 5 and it is noted that the claimed fragments do not exist as an invention independent of their function in encoding a protein, SEQ.ID.NO: 5. The actual structure or other relevant identifying characteristics of each protein fragment having the claimed properties of the protein can only be determined empirically by actually making every nucleic acid that encodes the recited fragments and testing each to determine whether such a fragment has the particularly disclosed properties of full length protein. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function. This specification does not teach functional fragments of SEQ.ID.NO: 5. There is no written description support for functional fragment thereof, at least 20 amino acids in length which shows immunological cross reactivity with said polypeptide, said polypeptide having haemolysin activity as claimed.

The isolated polypeptide comprising SEQ ID NO: 5 is uncharacterized by this specification and is asserted to belong to haemolysin family of proteins. The specification fails to teach the structure or relevant identifying characteristics of a representative number of SEQ.ID.NO: 5 fragments, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 U5PQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc V Chugai Pharmaceutical Co Ltd.*, 18 U5PQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 U5PQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

7. Claims 63, 66 and 72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide or a composition comprising the amino acid sequence SEQ ID NO: 5 does not reasonably provide enablement for functional fragment thereof, at least 20 amino acids in length which shows immunological cross reactivity with said polypeptide, said polypeptide having haemolysin activity The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are discussed supra,

The nature of the invention is preparation of recombinant polypeptides and its use a vaccine preparation against *Moraxella bovis* infection. The specification teaches the production of recombinant polypeptide comprising the amino acid sequence, SEQ ID NO: 5, which is encoded by *Moraxella bovis* strain Dalton 2d. The specification also teaches on page 25 that this full-length protein contains 928 amino acids with a molecular weight 98.8 kD. At the amino acid level it appears that this haemolysin gene product shows similarities with a subunit of the RTX and other haemolysins. However, the specification fails to teach functional fragment thereof, at least 20 amino acids in length which shows immunological cross reactivity with said

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polypeptide, said polypeptide having haemolysin activity. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid sequences (i.e. fragments) for different aspects of biological activity cannot be predicted a priori and must be determined empirically on a case-by-case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis in proteins. Such proteins differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition. Applicants have not taught which residues of SEQ ID NO: 5 can be varied and still achieve a polypeptide that is functional as a vaccine or is capable of use as a diagnostic using immunological means of recognition. Since, the specification lacks a written description of any fragment of SEQ ID NO: 5, it is not enabled for this language because it fails to enable the skilled artisan to envision the detailed chemical structure of the claimed polypeptide fragments of SEQ ID NO: 5. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Applicants' arguments filed on 7/27/04 have been fully considered but they are not deemed to be persuasive for the following reasons:

Applicant states as amended claims 63, 66 and 72 obviate the rejections because the amended claims recite functional fragments and the specification on page 9 defines the term "functional fragment".

The examiner disagrees with the applicant because the amended claims are not restricted to specific fragments of SEQ.ID.NO: 5 and further it is not clear how applicant is considering the immunological cross reactivity (epitope) as function since "cross reactivity"

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appears to be the property of a peptide. The claims broadly recite an isolated polypeptide comprising a functional fragment thereof at least 20 amino acids in length which shows immunological cross reactivity with said polypeptide and are not limited to the specific fragment of SEQ.ID.NO: 5 but reads on a polypeptide comprising 20 amino acids plus unlimited amino acids (the examiner considers these variants and hereafter will be referred to variants).

Therefore, such said variants do not meet the guidelines on written description.

The claims do not set forth an isolated polypeptide consisting of 20 contiguous amino acids of SEQ.ID.NO: 5 having haemolysin activity. Further the limitation "at least " in the claims does not limit to SEQ.ID.NO: 5 and reads on any polypeptide as long as it has minimum 20 amino acids. The specification does not recite what other polypeptides have immunological cross reactivity to what peptides. Thus, the specification fails to teach the claimed variants and does not satisfy the written description guidelines because an isolated polypeptide comprising (open language) at least 20 amino acids plus unlimited and unknown amino acids of SEQ.ID.NO: 5 would result in an unknown variants without sufficient structure and completely lacking identifying characteristics such as function. Thus, fragments as claimed are broader than SEQ.ID.NO: 5 and do not appear to have sufficient identifying characteristics. Further, immunological cross reactivity is not an identifying characteristic of a fragment because there are many fragments with the same characteristic in a polypeptide and such variants are not distinguishable from each other. Thus variants as claimed are uncharacterized by this specification and are not asserted to belong to any known family of proteins such as outer membrane proteins of *Moraxella bovis*. The specification fails to teach the structure or relevant identifying characteristics sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Therefore, the skilled artisan would not be able to use such broadly claimed fragments.

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Claim Rejections – 35 U.S.C. 102 maintained

Applicant states that the claims 63, 66, and 72 have been amended and thus these rejections are no longer applicable.

It is not clear to the examiner why and how these rejections are not applicable to the amended claims. However, the examiner's position on broadly claimed invention is discussed below for the newly amended claims.

8. The rejection of claims 63, 66 and 72 under 35 U.S.C. 102(e) as being anticipated by Campos et al U.S.Patent: 6,096,320 is maintained as set forth in the previous office action.

The claims are drawn to an isolated polypeptide comprising the amino acid sequence as set out in SEQ.ID.NO: 5 or a functional fragment thereof, at least 20 amino acids in length which shows immunological cross reactivity with said polypeptide, said polypeptide having haemolysin activity. Claims are also drawn to a composition comprising said polypeptide and optionally a carrier and/or adjuvant.

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Molecular Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of" represents closed claim language and excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F. 2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

Campos et al 1994 disclose an isolated recombinant P. hemolytic leukotoxin polypeptide fused to IL2 (IL2-LKT, see Example 1). This isolated polypeptide, SEQ.ID.NO: 2 comprises several functional fragments (see alignment of SEQ ID NO: 2 Db of the prior art with the disclosed SEQ.ID.NO: 5 Qy) having at least 20 amino acids, for example: from position 426-446 (see column 16, lines 40-56).

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Qy 8 KSNIQAGLNSTKSGLNLYLAIPKD--YDPQKGGTLDNFIKADELGIARLASEPNHTET 65
Db 173 QSLTQAG-SSLKTGAICKIILYIPQNYQYDTEQGNGLQDLVKAESLGIEVQREERNNIAT 231

Qy 66 AKKSVDTVNQFLSLTQTGIAISATKLEKFLQKHSTNKLAKGLDSVENIDRKLKASNVLS 125
Db 232 AQTSLGTIQTALGLTERGIVLSAPQIDKLQK---TKAGQALGSAESIVQNAKAKTVLS 288

Qy 126 TLSSFLGTALAGIELDSLIIKKGDAAPDALAKASIDLINEIIGNLSQSTQTIAPFSSQLAK 185
Db 289 GIQSLILGSLVLAGMDLDEAL-QNNNSQHALAKAGLELTNSLIENIANSVKTLDEFGEQISQ 347

Qy 186 LGSTISQAKGFSNIGNKLOML-NFSKTNLGLLEIITGLLSGISAGFALADKNASTGKVVAA 244
Db 348 FGSKLQNIKGLGTLDGDKLKNIGGLDKAGLGLOVISGLLSGATAALVLADKNASTAKKVG 407

Qy 245 GFELSNQVIGNVTKAISSVLAQRVAAGLSTTGAVAALITSSIMLAISPLAFMNAADKFN 304
Db 408 GFELANQVVGNIITKAVSSYILAQRVAAGLSTTGVAALIASTVSLAISPLAFAGIADKFN 467

Qy 305 HANALDEFAKQFRKFGYDGDHLLAEYQRGVGTIEASLTITSTALGAVSAGVSAAGVSAV 364
Db 468 HAKSLESYAERFKLGYDGDNLLAEYQRGVGTIDASVTAINALAAAGGVSAAGSVI 527

Qy 365 GTPIALLVAGVTGLISGILEASKQAMPESVANRLQKILEWEKQNGGQNYFDKGYDSRYA 424
Db 528 ASPIALLVSGITGVISTILQYSKQAMPEHVANKIHNKIWEKKNHNGQNYFENGVDARYL 587

Qy 425 AYLANNLKFLELNKELEAERVIAITQQRWDNNIGELAGITKLGERIKSGKAYADAFEDG 484
Db 588 ANLQDNMKFLNLNKELEAERVIAITQQQWDNNIGDLAGISRLGKVLGKAYVDAFEEG 647

Qy 485 KKVEAGSNITLDAKTGIIDISNSNGKKTQALHFTSPLLTAGTESRERLTNGKYEYINKLK 544
Db 648 KHIKADKLVLQDSANGIIDVSNNGKAKTQHILPRTPLLPTEHRERVTGKYEYITKLN 707

Qy 545 FGRVKMNVQVTDGEASSKLDPSKVIQV-----AETBGTDEIGLIVNAKAGNDDIFVGG 597
Db 708 INRVDSWKITDGAASSTFDLTNVVQRIGIELDNAGNVTKTKETKIIAKLGEQDDNVFVGS 767

Qy 598 GKMNIDGGDGHDRVFYSKDGFGNITVDGTSATEAGSYTVNRKVARGDIYHEVVVKROETK 657
Db 768 GTTEIDGGEYDRVHYSR-GNYGALTIDATKETEQGSYTVNRFVETGKALHEVTSTHTAL 826

Qy 658 VGKRTETIQYRDYELRKVGYGQSTONLKSVEEVIGSQFNDVFKGSKFNDI FHSGEQDDL 717
Db 827 VGNREEKIEYR-HSNNOHHAGYYTKDTLKAVEEIIIGTSHNDIFKGSKFNDAFNGGDGVD 885

Qy 718 LDGGAGDRLPGGKGNDRLSGDEGDDLLDGGSGDDVLNGGAGNDVYIFRKGDDNDTLVDG 777
Db 886 IDGNDGNDRLPGGKGGDIDGGGNGDDPIDGGKGNDLHGKGDDIFVHRKGGDNDIITDS 945

Qy 778 TGNDKLAPADANISDIMIERTKEGIIVKRNDHSGSINIPRWY---ITSNLQNYQSNKTD 833
Db 946 DGNDKLSFSDSNLKDLPKVKHNLVI-TNSKKEKVTIQNWPREADFAKEVPNYKATK-D 1003

Qy 834 HKIEQLIGKDSYITSQIDKILQDKKQGTVITSQELKKLADENKSQKLSASDIASSLNK 893
Db 1004 EKIEEYIGQNGERITSKQVDDL--AKGNGKITQDELSKVVDNYELLKHS-KNVTNSLDK 1060

Qy 894 LVGSMALFGTANSVSSNALQFITQPTQGI 922
Db 1061 LISSVSAPTSSNDSRNVLVAPTSMLDQSL 1089

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Further the disclosed polypeptide (SEQ.ID.NO: 2) shows immunological cross reactivity as it shares epitope (see Db above position 408-467) with said claimed polypeptide (SEQ.ID.NO: 5) as shown below.

LAQRVAAGLS
|||||||
LAQRVAAGLS

Thus the prior art also discloses isolated polypeptide (recombinant polypeptide P. haemolytica leukotoxin) and a composition comprising said peptide in phosphate buffered saline (i.e., carrier with Emulsigen as the adjuvant (see column 19, lines 1-11) and thus read on composition claim 72. Thus the prior art anticipated the claimed invention

9. The rejection of claims 63, 66 and 72 under 35 U.S.C. 102(b) as being anticipated by Billson, F. M. et al. (1994) FEMS Microbiology 124:69-73 is maintained as set forth in the previous office action.

The claims are discussed supra.

Billson et al disclose an isolated recombinant haemolysin antigen and a vaccine composition comprising said haemolysin antigen from the haemolytic strain M. bovis isolate UQV 148NF and each preparation formulated in incomplete Freund's adjuvant (see page 70, left column, under preparation of vaccine antigen through right column).

Applicant's use of the open-ended term "comprising" in claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed haemolytic vaccine antigens which inherently comprise functional fragments thereof, at least 20 amino acids in length which shows immunological cross reactivity with said polypeptide, said polypeptide having haemolysin activity. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art haemolytic antigen and the claimed fragments are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed fragments and composition having said fragments with the prior art haemolysin antigen and composition

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having said antigen the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 12, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Remarks

10. No claims are allowed.

Conclusion

11. This application contains 39-62, 67-71 and 73-84 drawn to an invention nonelected. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

12. **THIS ACTION IS MADE FINAL.** See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.


13. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

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14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


Padma Baskar Ph.D.


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